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EXAMINER	
LUKTON, DAVID	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action

The response filed 1/29/08, proposes to add claim 41. However, this amendment will not be entered. Claim 41 requires that the ghrelin (or analog) be administered prior to gastrectomization. While one or more claims may have encompassed this possibility, none previously required it. Note also that the declaration filed 1/29/08 is also not being considered at the present time.

Claims 1-10, 14, 15, 18, 20, 22, 27, 28, 30, 38-40 remain pending.

✧

Applicants have argued that claims 39-40 should be rejoined in the event that claim 1 is determined to be allowable. Applicants are certainly correct that the restriction should be revisited in the event that claim 1 is found allowable. That time is not yet at hand, however.

Claims 10, 18, 20, 39, 40 remain withdrawn from consideration; claims 1-9, 14, 15, 22, 27, 28, 30, 38 are examined in this Office action.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14, 15, 22, 27, 28, 30, 38 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As indicated previously, Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) discloses that once a vagotomy is performed, ghrelin loses all activity. Applicants have speculated as to why there might be a discrepancy between their observations and those of Asakawa. From a purely scientific perspective, it is the personal opinion of the examiner that applicants' speculation has some merit. But there are two other issues: First, patent examination is not purely about what might make sense to a scientist; it is also about weighing evidence from a legal perspective. Sometimes a scientific conclusion is contradicted by a legal conclusion. Second, another factor which could explain the discrepancy concerns applicants' use of MK-0677, which barely qualifies as a peptide, and which bears no structural relationship whatsoever to ghrelin. Maybe it is true that there is a common receptor which is activated, but that does not mean that significant differences do not exist with regard to pharmacological activity. Thus, if applicants were to repeat the experiments with ghrelin itself, applicants might well discover that body weight gain is minimal following vagotomy/ gastrectomy.

This ground of rejection will be maintained at the present time. However, in the event that the obviousness issues can be resolved, and in the further event that agreement can be reached on the question of whether the claims actually require

that a vagotomy accompany gastrectomy, it would become appropriate, at that point, to revisit this rejection.

A matter separate from the foregoing concerns claim 38. This claim recites the term "prophylactically effective". Even if it is true that ghrelin can mitigate loss of body weight, or that ghrelin can mitigate the state of cachexia, it does not follow therefrom that outright prevention can be achieved. In response to this ground of rejection, applicants have argued that the examiner should give full faith and credit to actions of prior examiners in the same application. Whatever the merits of this assertion, it has no relevance here. No other examiner has examined application 10/530866. Next, applicants have argued that if there are a significant number of examiners who have abstained from imposing a particular rejection, then all other examiners who follow are obligated to abstain from imposing the rejection in similar situations. However, this proposition is not true, and the court cases referred to do not really support it, at least in the case of enablement. Applicants have also argued that a substantial number of patents have issued in which the offending term is present. Applicants are advised that the examiner is acutely aware of the truth of this. Applicants are further advised that the examiner would be pleased to withdraw this ground of rejection if ordered to do so as a result of an appeal conference.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or

absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

As matters currently stand, "undue experimentation" would be required to practice the claimed invention.

✢

Claim 38 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is drawn to a method of treating disorders in a subject who has not actually undergone gastrectomy. At the same time, the claim requires that the disorder that is being treated be attributable to gastrectomy. Thus, there is a contradiction; which limitation controls?

✢

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention

was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 14, 15, 22, 27, 28, 30, 38 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or (ii) Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001).

As indicated previously, each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite. Accordingly, it would have been obvious to administer ghrelin to reverse the

adverse effects of weight loss caused by the gastrectomy. In response to the foregoing, applicants have argued that the claims require that vagotomy accompany gastrectomy. However, this is not what the claims require. If applicants would like to amend the claims to require that vagotomy accompany gastrectomy, applicants are free to do this.

Applicants have also argued that in the event that the examiner chose to withdraw the rejection over Asakawa, this would constitute a new ground of rejection. However, applicants are mistaken. For example, a §103 over each of the following combinations remains in force: Zittel in view of Wren, Saidi in view of Wren, and Liedman in view of Wren.

Applicants' attempt to submit a declaration is acknowledged; however, it will not be considered at the present time.

The claims remain prima facia obvious.

✦

Claims 1-9, 38 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or (ii) Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) further in view of Kojima,M. (Nature 402 (6762), 656-660, 1999).

As indicated above, each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite. Kojima provides the sequence of ghrelin.

As noted above, an important issue is whether or not the claims require that vagotomy accompany gastrectomy. In the event that agreement can be reached on this issue, the prosecution will move a significant distance towards disposal. It appears at the present time that applicants would like the vagotomy to be implicit for purposes of prosecution, but absent for purposes of enforcement (of the issued patent). Insofar as prosecution is concerned, it is suggested that applicants do one of the following: (a) amend the claims to require that vagotomy occur, or (b) abstain from arguing that vagotomy is implicit.

As matters currently stand, the claims remain obvious.

✦

Claims 1-9, 38 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or (ii) Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) further in view of Hosoda,H. (*J. Biol. Chem.* **278**(1), 64-70, 2003)

As indicated above, each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite.

Thus, the claims remain obvious.

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Claim 38 is rejected under 35 U.S.C. §103 as being unpatentable over Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001).

As indicated previously, each of Wren and Asakawa disclose that ghrelin stimulates appetite.

Claim 38 encompasses a method of inhibiting loss of appetite in a subject who has not actually undergone gastrectomy. Claim 38 requires only that the person have the intent to have the surgery done at some point in the future. The "future" could be 2 weeks, or the future could be 20 years hence. As such, the phrase "prior to gastrectomization" exerts little impact. As it happens, a persons' intent with regard to elective surgery has no bearing on his (or her) physiological response to a peptide.

Thus, the claim is rendered obvious.

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Claim 38 is rejected under 35 U.S.C. §103 as being unpatentable over Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95,

2001) or Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) further in view of Hosoda,H. (*J. Biol. Chem.* **278**(1), 64-70, 2003)

The arguments presented above (the §103 over Wren or Asakawa) apply here as well.

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- Reference "CB" was stricken from the IDS. What is suggested is that the following be cited on the "other documents" section:

  Claims 1-7 of WO 02/060472.

  This will make it clear to others reviewing the prosecution that only claims 1-7 have been considered. Applicants have argued that they are permitted to submit foreign language documents. This is certainly true. But it is equally true that an understanding of the Japanese language is not a requirement for U.S. patent examiners. Note also that the examiner is not requiring a translation of WO 02/060472. Rather, the examiner is requiring only clarity of the record. If applicants are satisfied that the examiner has no knowledge of the contents WO 02/060472 other than claims 1-7, applicants should feel no reluctance to make this clear on the record.

- Similar to the foregoing, by initialing reference "CE" on the IDS filed 1/29/08, the examiner would be signaling that he has read the entire document, which is not the case. The following format is suggested:

  Abstract of Tanikawa (*Adv Med Sci* 155 623, 1990).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654